NDA 17-643/S-060
NDA 18-449/S-027

Fresenius Kabi Clyaton, L.P.
Attention: Rosemary P. Davis, R.A.C.
Manager of Regulatory Affairs
P.O. Box 597
8484 US 70 West
Clayton, North Carolina 27520

Dear Ms. Davis:

Please refer to your supplemental new drug applications dated July 7, 1995, received July 10, 1995, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA 17-643/S-060 Intralipid 10% (I.V. Fat Emulsion) Injection
NDA 18-449/S-027 Intralipid 20% (I.V. Fat Emulsion) Injection

These "Changes Being Effected" supplemental new drug applications provide for changes in the PRECAUTIONS and OVERDOSAGE sections of the package inserts to resemble Intralipid 30% (I.V. Fat Emulsion) Injection (NDA 19-942), which was approved on December 30, 1993, as follows:

PRECAUTIONS

Carcinogenesis, Mutagenesis, Impairment of Fertility: Studies with Intralipid® have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Nursing Mothers: Caution should be exercised when Intralipid® is administered to a nursing woman.

Pediatric Use: See DOSAGE AND ADMINISTRATION.

OVERDOSAGE

In the event of fat overload during therapy, stop the infusion containing Intralipid® *[strength]* until visual inspection of the plasma, determination of triglyceride concentrations, or measurement of plasma light-scattering activity by nephelometry indicates the lipid has cleared. Re-evaluate the patient and institute appropriate corrective measures. See WARNINGS and PRECAUTIONS.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted July 7, 1995).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 17-643/S-060, 18-449/S-027." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Samuel Y. Wu, Pharm.D., Regulatory Project Manager, at 301-827-6431.

Sincerely,

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research